

1 APPARATUS AND METHOD FOR PREVENTING FLUID TRANSFER BETWEEN  
2 AN OVIDUCT AND A UTERINE CAVITY

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5 Field of the Invention

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7 This invention concerns birth control and, more  
8 particularly, apparatus and methods for preventing fluid  
9 from passing into an oviduct of a female reproductive  
10 system.

11

12 Background of the Invention

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14 In certain circumstances, birth control can be very  
15 important, and as such, great effort and research has been  
16 expended in this area. There are two primary areas of  
17 birth control for female use, other than surgery, including  
18 pharmaceutical, and mechanical approaches. Prescription  
19 birth control drugs are frequently used, but are expensive  
20 and can have adverse physical or mental side effects.  
21 Additionally, missing a dosage can have significant effects  
22 on the reliability of the treatment. To avoid these  
23 problems, many women rely on less expensive mechanical  
24 devices as a means for inhibiting conception.

1       Nearly all mechanical birth control devices and  
2 techniques attempt to block fluid transfer between either  
3 the vagina and the uterus or the oviducts and the uterus.  
4 By preventing fluid transfer between the uterus and the  
5 vagina and/or the oviducts; conception is prevented or at  
6 least minimized. Although existing mechanical devices and  
7 techniques prove adequate, they are often unreliable and  
8 difficult to construct and install. Temporary mechanical  
9 devices typically do not provide complete blockage  
10 resulting in a greater chance of conception. Permanent  
11 mechanical devices provide more reliable blockage,  
12 providing an almost complete prevention of conception, but  
13 are often difficult to install and expensive.  
14 Additionally, the installation is not reversible.

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16       Thus, there is a need for a device for preventing  
17 conception that is easy to construct, easy to install, safe  
18 to use and that resists the occurrence of infection over an  
19 extended period of time.

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21       It would be highly advantageous, therefore, to remedy  
22 the foregoing and other deficiencies inherent in the prior  
23 art.

1       Accordingly, it is an object of the present invention  
2   to provide a new and improved apparatus and methods for  
3   preventing fluid from passing into an oviduct of a female  
4   reproductive system.

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6       Another object of the invention is to provide  
7   apparatus for preventing fluid transfer through an opening  
8   connecting an oviduct to a uterine cavity.

9

10      And another object of the invention is to provide  
11   apparatus for preventing fluid transfer through an opening  
12   connecting an oviduct to a uterine cavity which is  
13   extremely effective and can be reversed.

1                   Summary of the Invention

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3         The above problems and others are at least partially  
4         solved and the above purposes and others realized in new  
5         and improved apparatus for preventing fluid transfer  
6         through an opening connecting an oviduct to a uterine  
7         cavity. The apparatus includes a body having a base with a  
8         periphery and a seal carried by the body for overlying and  
9         engaging uterine tissue leading to the opening. The seal  
10       receives fibroblast in-growth to create a hermetic seal  
11       between the oviduct and the uterine cavity. A peripheral  
12       anchor portion extends from the base for securing the body  
13       to the uterine tissue leading to the opening, the base  
14       overlying the opening.

15

16         The peripheral anchor may include a plurality of  
17         spikes extending from the periphery of the base. The  
18         spikes can terminate in a tissue engaging structure such as  
19         barbs. The peripheral anchor portion can also include a  
20         plurality of helical blades extending radially outwardly  
21         from the base. The helical blades can be carried by a  
22         blade disk coupled to the base or be integral with the  
23         base. The body supports an engaging member that may be  
24         rigidly grasp by a tool and which allows the apparatus to

1   be manipulated during installation.

2

3       Consistent with the foregoing, associated methods of  
4   preventing fluid transfer through an opening connecting an  
5   oviduct to a uterine cavity may also be provided.

1                   BRIEF DESCRIPTION OF THE DRAWINGS

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3                 The foregoing and further and more specific objects  
4         and advantages of the instant invention will become readily  
5         apparent to those skilled in the art from the following  
6         detailed description of a preferred embodiment thereof  
7         taken in conjunction with the drawings, in which:

8

9                 Fig. 1 is a perspective view of apparatus for  
10      preventing fluid transfer between an oviduct and a uterine  
11      cavity of a female reproductive system;

12

13                 Fig. 2 is a partial sectional side view of the  
14      apparatus of Fig. 1;

15

16                 FIG. 3 is an end view of the apparatus of Fig. 1;

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18                 Fig. 4 is a view showing the apparatus of Fig. 1 as it  
19      would appear being installed;

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21                 Fig. 5 is a view showing the apparatus as it would  
22      appear installed with a female reproductive system for  
23      preventing fluid transfer between an oviduct and a uterine  
24      cavity;

1       Fig. 6 is a perspective view of another embodiment of  
2   apparatus for preventing fluid transfer between an oviduct  
3   and a uterine cavity of a female reproductive system;

4

5       Fig. 7 is a side view of the apparatus of Fig. 6; and

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7       FIG. 8 is an end view of the apparatus of Fig. 6 with  
8   the seal removed.

1           DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT

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3         Turning now to the drawings, in which like reference  
4         characters indicate corresponding elements throughout the  
5         several views, attention is first directed to Fig. 1  
6         illustrating a perspective view of apparatus 10 for  
7         preventing fluid transfer between an oviduct and a uterine  
8         cavity of a female reproductive system. Apparatus 10  
9         includes a stop or seal 11 supported by a body 12. As can  
10       be seen in this embodiment, seal 11 has a circular disk  
11       shape and body 12 includes a circular base 14. It will be  
12       understood that while a circle is the preferred shape,  
13       other shapes, such as a square, an octagonal, etc., can be  
14       used. Referring also to Figs. 2 and 3, body 12 is  
15       constructed of rigid, non-porous, bio-compatible material  
16       such as stainless steel, titanium, ceramics or a poly-base  
17       material. Body 12, or portions thereof, can also be formed  
18       of a biodegradable compound which will dissolve and be  
19       absorbed by the body over a period of time. The material  
20       is absorbed, flushed or eliminated by the human body over a  
21       certain period of time after installation. The  
22       biodegradable material may be any suitable material such as  
23       any one or more of a variety of biodegradable polymers such  
24       as polyglycolide and polyactide, and copolymers of

1 glycolide and lactide, trimethylene carbonate, and  
2 caprolactone and the like. In this instance, only seal 11  
3 will remain, or various portion of the body may remain if  
4 not formed of absorbable material. Body 12 includes a  
5 peripheral anchor portion which holds body 12 and seal 11  
6 in position on the uterine wall as will be described  
7 presently, and an extension portion 18.

8

9       The peripheral anchor portion, in this embodiment,  
10 includes a plurality of spikes 20 extending perpendicularly  
11 from the periphery of base 14 of body 12, and passing  
12 through seal 11. While spikes 20 pass through seal 11 in  
13 this embodiment, it will be understood that the diameter of  
14 seal 11 may fit within the circle of spikes 20. Each of  
15 spikes 20 includes a shaft 22 terminating in a tissue  
16 engaging structure. In this embodiment, the tissue  
17 engaging structure is a barbed head 24. One skilled in the  
18 art will understand that other engagement structures can be  
19 employed. For example, one or more barbs may be employed,  
20 or the tissue engagement structure can be a conical  
21 enlargement. The enlargement leads with a point or vertex,  
22 and trails with a base or directrix that defines a step  
23 angle with shaft 22. The directrix defines a diameter  
24 greater than the outer diameter of shaft 22.

1 Seal 11 is a disk of material coupled to base 14 by a  
2 fastener, such as adhesives or a central plug 26 received  
3 within a socket of body 12 as in the present embodiment.  
4 Seal 11 may also a continuous annular body having a central  
5 opening fitting around a projection from base 14, or  
6 attached by a fastener such as a rivet, screws, spikes or  
7 the like. Seal 11 is preferably fabricated of a somewhat  
8 or highly deformable, porous material. In a preferred  
9 embodiment, body 20 is constructed of  
10 polytetrafluoroethylene (PTFE) plastic which, is a well  
11 known material sold under the trademark TEFLO.  
12 Appropriate porous PTFE materials are commercially  
13 available and may be produced by the process described in  
14 Japanese Patent Publication No. 135,60/67 and U.S. Pat. No.  
15 3,953,566, which are incorporated by reference herein.  
16 Other acceptable porous materials manufactured and sold  
17 under the trademarks PROPLAST, DACRON or GORETEX may also be  
18 used for seal 11. Included in a list of preferred  
19 materials for seal 11 is cotton, polypropylene or silk  
20 mesh. Seal 11 defines micro porous fibrous structure  
21 consisting of small fibers and nodes connected together.  
22 Similar expanded PTFE products are presently in use for  
23 vascular prostheses and typically include pore sizes on the  
24 order of two microns or greater. Typical pore size for

1 most effective utilization in vascular prostheses generally  
2 falls within the range of between approximately five to ten  
3 microns.

4

5 Regarding Figs. 1 and 2, body 12 includes extension 18  
6 that extends from base 14 away from spikes 20. In a  
7 preferred embodiment, extension 18 includes an inner end  
8 30, an outer end 32 and an engaging member 34 positioned,  
9 in this specific embodiment, at or adjacent outer end 32.  
10 Engaging member 34 is intended to be substantially any  
11 structure allowing gripping by an insertion tool. Member  
12 34 can be a ball joint, a ball joint with flat portion to  
13 allow rigid gripping or various other shapes such as  
14 cuboidal, hexagonal and the like.

15

16 Turning now to Figs. 4 and 5, shown is an utero-tubal  
17 junction of a female reproductive system including a  
18 uterine cavity wall 40, and an opening 42 leading to an  
19 isthmus of an oviduct. To install apparatus 10, a guide  
20 catheter may be maneuvered into the uterine cavity by way  
21 of the vagina and the cervix. The catheter is preferably  
22 flexible which allows it to be easily maneuvered into the  
23 uterine cavity. The catheter preferably includes the  
24 operating channel of a hysteroscope, which is a

1 commercially available device used primarily by  
2 gynecologists for examining and operating on the female  
3 reproductive system. A typical hysteroscope typically  
4 includes three parallel oriented channels that run  
5 longitudinally along a given length of the device. One of  
6 these channels provides a source of illumination, and  
7 second channel includes a fiberoptic bundle that provides  
8 illumination. The third channel can house a flexible guide  
9 having flexible jaws or tongs that can engage engaging  
10 member 34. The guide includes a mechanism that a physician  
11 may operate for moving the tongs between an open condition  
12 and a closed condition for engaging ball joint 34. By  
13 maneuvering the guide through the catheter, apparatus 10  
14 can be positioned, with spikes 20 of the anchor portion  
15 surrounding opening 42. The spikes are then embedded in  
16 the tissue surrounding opening 42 as shown in Fig. 5.  
17 Engaging member 34 permits apparatus 10 to be securely held  
18 and articulated as needed relative to the placement device  
19 for providing a natural and easy alignment and anchoring of  
20 body 12 overlying opening 42. The fiberoptic bundle and  
21 the illuminating ability of the catheter allow the  
22 physician to visually identify opening 42.

23

24 With spikes 20 facing opening 42, shafts 22 may be

1 easily inserted into the tissue around opening 42. Barbs  
2 24 provide for a smooth insertion into the tissue, and  
3 provide an anchor holding apparatus 10 in position. When  
4 properly positioned, outer edges of seal 11 overlie and  
5 rest against the surface of uterine tissue leading to and  
6 defining opening 42 as shown in Fig. 5. Body 12 maintains  
7 a desired alignment between seal 11 and the uterine tissue  
8 leading to and defining opening 42. Once body 12 is  
9 anchored with seal 11 positioned against the uterine tissue  
10 leading to and defining opening 42, fibroblast in-growth  
11 between that surrounding uterine tissue and seal 11  
12 commences immediately to form an initially weak but  
13 progressively stronger bond between seal 11 and the uterine  
14 tissue. Body 12 cannot be easily moved out of position due  
15 to the influence of the anchor portion. Spikes 20 firmly  
16 hold body 12 over opening 42, preventing apparatus 10 from  
17 inadvertently falling away from the oviduct. Thus, the  
18 anchor portion holds body 12 in position so that seal 11  
19 can accept immediate fibroblast in-growth to provide a  
20 hermetic seal and fluid isolation between the oviduct and  
21 uterine cavity.

22

23       Apparatus 10 may be removed, even after fibroblast in-  
24 growth is complete, by grasping engaging member 34, such as

1 with tongs, and forcibly removing apparatus 10. Because  
2 uterine and oviduct tissue is very resilient, tissue damage  
3 caused by the forcible removable of apparatus 10 heals very  
4 quickly.

5

6 Referring now to Figures 6, 7 and 8, another  
7 embodiment of apparatus for preventing fluid transfer  
8 between an oviduct and a uterine cavity of a female  
9 reproductive system, generally designated 50, is  
10 illustrated. Apparatus 50 is substantially identical to  
11 apparatus 10 in structure and function, and includes  
12 substantially the same elements. Accordingly, the  
13 reference characters used to describe apparatus 10 will  
14 also be used to describe apparatus 50, but only to the  
15 extent of their common structural components. For clarity,  
16 common reference characters used to describe apparatus 50  
17 will include a prime ("') symbol. In this regard,  
18 apparatus 50 includes seal 11' and body 12'. Body 12'  
19 includes a base 14', a peripheral anchor portion and an  
20 extension portion 18'. Rather than providing a plurality  
21 of spikes as in apparatus 10, the peripheral anchor of  
22 apparatus 50 includes a helical blade disk 52 having a pair  
23 of opposing helical blades 53 and 54 extending therefrom.  
24 Blade disk 52 is fastened securely and rigidly to base 14'

1 by fasteners such as rivets screws, adhesives, etc. It  
2 will be understood that while a blade disk 52 is coupled to  
3 base 14' in the preferred embodiment, the blades can be  
4 formed integrally with body 12' and extend from base 14'.

5

6       In use, apparatus 50 is positioned over an opening 42  
7 of an oviduct employing, for example, a device as described  
8 previously for apparatus 10. When positioned with seal 11'  
9 overlying opening 42, apparatus 10 is rotated causing  
10 blades 53 and 54 to enter the uterine wall. The helical  
11 shape causes blades 53 and 54 to pull body 12' and seal 11'  
12 firmly against the uterine wall overlying opening 42 and  
13 anchoring seal 11' in position. As a result, apparatus 50  
14 cannot be easily moved out of position. Like spikes 20,  
15 blade disk 52 cooperates as a peripheral anchor that holds  
16 body 12' in place so that seal 11' can accept immediate  
17 fibroblast in-growth to provide a hermetic seal and fluid  
18 isolation between the oviduct and the uterine cavity.

19

20       The present invention has been described above with  
21 reference to a preferred embodiment. However, those  
22 skilled in the art will recognize that changes and  
23 modifications may be made in the described embodiments  
24 without departing from the nature and scope of the present

1 invention. For example, while apparatus 50 employs helical  
2 blades as the peripheral anchor they may be developed more  
3 in the form a screw threads. Thus, apparatus 50 could be  
4 threaded into tissue with a continuous helical blade in the  
5 form of screw threads instead of two or more blades.  
6 Various changes and modifications to the embodiment herein  
7 chosen for purposes of illustration will readily occur to  
8 those skilled in the art. To the extent that such  
9 modifications and variations do not depart from the spirit  
10 of the invention, they are intended to be included within  
11 the scope thereof which is assessed only by a fair  
12 interpretation of the following claims.

13

14 Having fully described the invention in such clear and  
15 concise terms as to enable those skilled in the art to  
16 understand and practice the same, the invention claimed is: